

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant | : Peter Kinast et al. | Art Unit | : 3797 |
| Serial No. | : 10/542,823 | Examiner | : William R. Carpenter |
| Filed | : July 24, 2006 | Conf. No. | : 8435 |
| Title | : A NEEDLE FOR PENETRATING A MEMBRANE | | |

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the action mailed June 2, 2008, Applicants elect the invention of Group 1 including claims 56-87 drawn to a needle for penetrating a membrane. The election is made with traverse.

Applicants submit that the shared special technical feature of rounded outer edges in the independent method and device claims is not disclosed in the references cited by the Examiner and request withdrawal of the requirement for restriction. Alternatively, Applicants request rejoinder of the claims upon allowance of the elected claims.

Doyle (US 5 752 942) discloses a beveled needle tip formed from a plurality of bevels, wherein the "intercepts" established at the transitions between different bevels are made less pronounced, *i.e.*, the height of the intercepts is reduced. The outer edges of the needle are sharp since they are defined by forming bevels at various angles to the central axis of the needle and are not rounded after the bevels have been formed. Thus, the outer edges of the needle in the area between the needle's apex (36) and a position beyond the needle's opening (fluid opening 22) are not rounded. **Doyle merely discloses the rounding or smoothing of the intercepts between needle bevels to provide "a more continuous, unitary bevel face [that] would require less penetration force" and therefore cause less pain upon insertion. (See col. 2, lines 15-30).**

Doyle does not disclose any rounding of outer edges of the needle beyond the needle opening. Accordingly, Applicants submit that this special technical feature is not found in the reference cited in the restriction requirement.

Other References Raised in Telephonic Interview circa 5/19/2008

Baldwin (US 3 071 135) explains (with reference to figures 5 and 6) that coring occurs when the flap cut by the leading edges of a lancet flexes downwardly to accommodate the needle and, in so doing, bears against the rear heel edge of the needle of the downwardly moving needle (See col. 3, lines 10-26).

Baldwin proposes to address coring by providing the heel of a beveled needle face with an external recess (17) that merges with an edge portion of the lumen opening. The "rear edge portion 18 is rounded . . . and merges with the smooth surface of heel recess 17." (col. 3, lines 53-56). Baldwin does not, however, disclose any rounding of the outer edges of the needle in the area between the needle's point and a position beyond the needle's opening, *i.e.*, the forward edges of the needle that penetrate the membrane.

Baldwin actually leads a skilled person away from the claimed invention, because Baldwin attempts to address coring by leaving a small portion of the core attached at the location of the recess in the heel, but otherwise allows coring along the remaining needle periphery.

In contrast, a needle according to the claimed invention includes outer edges in the area between the needle's point and a position beyond the needle's opening that are rounded. These rounded edges reduce coring by displacing the membrane.

Saito (US 5 575 780) and Utterberg (US 5 536 259) merely disclose needle points comprising a plurality of bevels.

Thus, Applicants submit that the claims of Group 1 and 2 have a common special technical feature that is not disclosed in the cited references and request withdrawal of the restriction requirement.

Accordingly, Applicants submit that claimed invention is patentable with respect to the references cited by the Examiner.

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Attorney's Docket No.: 19497-002US1 / P16657US01

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment. Applicants respectfully request consideration of all filed IDS' not previously considered, by initialing and returning each Form 1449.

Applicant requests a one month extension of time. All fees are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 19497-002US1.

Respectfully submitted,

Date: July 30, 2008

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